



UNITED STATES PATENT AND TRADEMARK OFFICE

cll

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/736,471

12/15/2003

Louis Kunkel

13407-050001

3473

26161

7590

04/24/2006

FISH & RICHARDSON PC

P.O. BOX 1022

MINNEAPOLIS, MN 55440-1022

EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/736,471	Applicant(s) KUNKEL ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, drawn to methods for gathering data related to a genetic factor and methods for evaluating a subject, classified in class 435, subclass 6.
- II. Claims 22-39, drawn to methods for mapping a genetic locus, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of invention I and II differ with respect to the reagents used to perform the method, the steps required to perform the method and the outcome or effect of the method. In particular, the method of invention I requires DNA from a subject and a reference sequence and involves amplifying a segment of DNA from a subject and comparing the segment to a reference sequence in order to accomplish the objective of gathering data related to genetic factors that influence longevity or to accomplish the objective of evaluating a subject. The method of invention II requires the use of a plurality of sibships of reference ages and a plurality of markers, and involves genotyping DNA

Art Unit: 1634

samples for markers from each individual of a sibship and determining a LOD score for each marker in order to accomplish the objective of mapping a genetic locus.

3. Further, inventions I and II are subject to an additional restriction requirement as follows.

Claims 14-19, with respect to invention I and claims 29, 30 and 36-39 with respect to invention II are subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

Specifically, claims 14-19 are drawn to methods which evaluate an individual for the distinct diseases selected from the group consisting of Alzheimer's disease, cancer, ocular disease, heart disease, cardiovascular disease and stroke. Claims 29, 30 and 36-39 are drawn to methods which perform LOD and association studies to evaluate the association between a marker and a condition selected from the group consisting of Alzheimer's disease, cancer, ocular disease, heart disease, cardiovascular disease and stroke. Each of these disorders have distinct etiologies and symptomologies and would be expected to be linked with different markers of chromosome 4 at different frequencies. Given the differences in the biological effects and outcome of each of these disorders and the fact that the recited disorders do not share a common property responsible for their claimed relationship, the Markush group set forth in claims 14-19, 29, 30 and 36-39 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement.

A search for each of these diverse disorders would not be co-extensive with one another. For example, a search for methods for identifying a marker linked to

Art Unit: 1634

Alzheimer's disease would not be coextensive with a search for methods for identifying a marker linked to cancer. Further, a reference which renders obvious or non-novel methods for identifying a marker linked to Alzheimer's disease would not also necessarily render obvious or non-novel methods for identifying a marker linked to cancer. Similarly, a finding that methods for identifying a marker linked to Alzheimer's disease are novel and unobvious over the prior art would not necessarily extend to a finding that methods for identifying a marker linked to cancer are also novel and unobvious over the prior art. Accordingly, a search of more than one of the disorders as claimed in claims 14-19, 29, 30 and 36-39 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. Accordingly, Applicants are required to elect one of the recited disorders. Note that this is not a species election.

Claims 1-13, 20, and 21 link the individual disorders of claims 14-19 and claims 22-28, and 31-35 link the individual disorders of claims 29, 30 and 36-39. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double

Art Unit: 1634

patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their recognized divergent subject matter. Further, a search for inventions I and II requires different keyword searches that are not co-extensive. For example, a search for methods for gathering data and evaluating a subject require different keyword searches as compared to a search for methods for mapping a genetic locus. Additionally, a finding that methods for gathering data and evaluating a subject are novel and unobvious would not necessarily extend to a holding that the methods for mapping a genetic locus are also novel and unobvious. Similarly, a search indicating that the methods for gathering data and evaluating a subject were known or would have been obvious would not necessarily extend to a holding that the methods for mapping a genetic locus are also known and obvious. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if

Art Unit: 1634

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
April 19, 2006


CARLA J. MYERS
PRIMARY EXAMINER